Exhibit H

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IN RE: PELVIC MESH/GYNECARE LITIGATION	:SUPERIOR COURT OF NEW JERSEY :LAW DIVISION - ATLANTIC COUNTY : :MASTER CASE 6341-10 : :CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

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September 13, 2012

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Volume II of the transcript of the Deposition of CHARLOTTE OWENS, M.D., called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure, by and before JoRita B. Meyer, a Certified Realtime Reporter, Registered Merit Reporter, and Certified Court Reporter for the State of Georgia, at the offices of Troutman Sanders, 600 Peachtree Street Northeast, Atlanta, Georgia, commencing at 9:11 a.m.

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A. Correct.
Q. And it says the potential effect of that is damage to the cannula and the potential hazard what could occur would be tissue damage, correct?
A. Correct.
Q. And the potential harm that could result here is described as bleeding, correct?
A. Correct.
Q. And you understood that through your review of this -- rephrase.
And you understood that it was required that you capture all of the different failure modes, all the things that could go wrong in the procedure, even if the doctor was properly trained and following the proper procedure, and the effects of those failure modes, the hazards that could occur, and the resulting harms, and you were supposed to capture all of them, correct?
A. Yes, all that we could conceive of, yes.
Q. Now, one of the things that could happen is during the passage of the guides, is the pudendal nerve could be injured, correct?

specifically mentioned in the document.

BY MR. SLATER:

Q. And therefore, none of them are specifically scored, correct?

A. They would have been included in things other than the terms that you mentioned.

Q. As the document appears and as it was specifically and carefully written by quality engineering, with your approval, those items do not appear and are not specifically scored, correct?

A. Those items are not specifically mentioned, no.

Q. All right. Now let's look at the dFMEA, which is Exhibit 629. You understood the purpose of the dFMEA, correct?

A. Yes.

Q. That's the Design Failure Modes and Effects Analysis, correct?

A. Yes.

Q. And what was the purpose of this analysis?

A. To review the potential risk associated with the design of the product.

Q. And when you say "associated with the

design of the product," that means that when the product is in a woman's body and the product was manufactured completely consistent with the specifications, these are the things that could go wrong and harm a patient, correct?

A. Correct.

Q. Let's look now at this dFMEA, and let's look at page -- looking at the Bates number 03573, the actual chart and grid.

And it indicates that you were one of the individuals who provided input as medical director, correct?

A. Yes.

Q. And again, as with the aFMEA, you had to sign off on the dFMEA in order for this gate to be surpassed so the product could move closer to Product Release Authorization and to be marketed to be put in women's bodies, correct?

A. Correct.

Q. And what this does is, in the chart, is the different components of the PROLIFT kit are each evaluated in terms of what harms they could cause if they were to fail, correct?

what occurred during the surgery going forward in time, correct?

A. Not going forward in an indefinite amount of time, no.

Q. Oh, no, how long forward?

A. Again --

Q. What's the cutoff?

A. There's not --

Q. I'm asking you for the cutoff.

A. I don't have an exact number of minutes or seconds. But I can tell you that it is about the application of the device, which is a surgical procedure.

MR. SLATER: Can you put, Diane, in front of her Exhibit 623?

MS. WATKINS: Yes. She's got it.

BY MR. SLATER:

Q. Doctor, this is the design -- rephrase.

Exhibit 623 is the final version of the Device Design Safety Assessment, the DDSA.

Do you see that?

A. I do.

Q. And you ultimately needed to sign off on the DDSA on behalf of Medical Affairs,

correct?

A. I'm trying to verify -- I'm not listed on the approval page.

Q. Do you recall whether or not you had to sign off on and approve the DDSA on behalf of Medical Affairs?

A. Again, as you know, it would have been seven years since I saw this document. I would need to see -- if I'm on there as an approver, then I can say I would have had to approve it. But right now I'm not remembering if I was an approver of this document.

Q. Can you look at the page that has in the bottom right corner, 812. That's the last three digits of the Bates number.

A. Okay.

Q. That's actually the first page of the DDSA form.

A. Yes.

Q. This form is the form that actually rates -- lists and rates the hazards as part of the DDSA, correct?

A. It appears that this is the DDSA safety assessment form, yes.

Q. And, for example, line 1 evaluates

biocompatibility hazards, correct?

A. Yes.

Q. For example, the second -- third -- second part of that, Implant device is not biocompatible, correct?

A. Correct.

Q. And now on the next page, for example, Section 5, Hazards resulting, it says "to," but it actually should say "from" the use of the device.

Do you see that?

A. Yes.

Q. And this lists different hazards that can result when the PROLIFT is utilized, correct?

A. Correct.

Q. And did you understand -- well, rephrase.

And then you go to the next page -- rephrase.

Then you go to number 6. It talks about hazards resulting from reasonably foreseeable misuses of the device.

Do you see that?

A. Yes.